



#20  
6.3.00  
RP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Griffith-Cima, et al. Examiner: D. Naff  
Serial No.: 09/008,945 Art Unit: 1651  
Filed: January 20, 1998 Docket No: 0492611-0315(MIT6196)  
For: TISSUE FORMATION BY INJECTING A CELL-POLYMERIC SOLUTION  
THAT GELS IN VIVO

COMMISSIONER OF PATENTS  
WASHINGTON, DC 20231

Sir:

**DECLARATION UNDER 37 C.F.R. 1.132**

I, Anthony Atala, declare as follows:

1. I am an inventor of the subject matter disclosed and claimed in United States patent application Serial No. 09/008,945 filed January 20, 1998 and entitled "TISSUE FORMATION BY INJECTING A CELL-POLYMERIC SOLUTION THAT GELS IN VIVO". This application claims priority to United States patent application Serial No. 08/056,140 now issued U.S. Patent No. 5,709,854, by Griffith-Cima et al. entitled "Tissue Formation by Injecting a Cell-Polymeric Solution that Gels In Vivo", filed on April 30, 1993.
2. The inventors of the '945 application are Linda Griffith-Cima, Anthony Atala, Charles A. Vacanti, and Keith T. Page. Dr. Griffith-Cima has changed her name to Linda Griffith since the application was filed.
3. This Declaration is presented for the purpose of removing from consideration by the Examiner a paper entitled "Injectable Alginate Seeded with Chondrocytes as a Potential Treatment for Vesicoureteral Reflux" by Anthony Atala, Linda G. Cima, Woosob Kim, Keith T. Paige, Joseph P. Vacanti, Alan B. Retik, and Charles A. Vacanti (*Journal of Urology*, Volume 150, pages 745-747, August 1993).

4. In 1992, I was a co-author on a presentation at the 1992 Annual Meeting of the American Academy of Pediatrics, Section on Urology. The content of this presentation is described by an abstract by Anthony Atala, Charles A. Vacanti, and Alan Retik, entitled "Cartilage Cells as a Potential Treatment for Reflux", American Academy of Pediatrics, 1992 Annual Meeting, Section on Urology Program for Scientific Sessions, San Francisco, CA, Saturday, October 10-12, (1992). The conference began on October 10, 1992, at which time the above-referenced abstract was available to the public in this country. The present declaration establishes that only the 1992 abstract and not the *Journal of Urology* paper was available to the public at the 1992 Annual Meeting.

5. The material made available to the public at the 1992 Annual Meeting is entirely described by the abstract co-authored by Atala, Vacanti, and Retik.

6. The *Journal of Urology* paper was not available to the public during the conference. It was published in August, 1993.

7. All statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patents issued thereon.



\_\_\_\_\_  
Anthony Atala, M.D.

4 - 27 - 00

\_\_\_\_\_  
Date

Exchange.3116406.1